February 11, 2004

PATENT APPLICATION DOCKET NO.: 3506.1000-002

IN THE UNITED STATES P

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Steven B. Landau

Application No.:

10/757,364

Group Art Unit: Unknown

TRADEMARK OFFICE

Filed:

January 13, 2004

Examiner:

Unknown

Confirmation No.:

Unknown

Title:

METHOD OF TREATING FUNCTIONAL BOWEL DISORDERS

CERTIFICATE OF MAILING OR TRANSMISSION I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States. Patent and Trademark Office on: 2.11.04 ignature

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:	
This I	Information Disclosure Statement is submitted: under 37 CFR 1.129(a), or (First/Second submission after Final Rejection)
[X]	under 37 CFR 1.97(b), or (Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
[]	under 37 CFR 1.97(c) together with either: [] a Statement under 37 CFR 1.97(e), as checked below, or [] a \$180.00 fee under 37 CFR 1.17(p), or (After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
[]	under 37 CFR 1.97(d) together with: [] a Statement under 37 CFR 1.97(e), as checked below, and [] a \$180.00 fee under 37 CFR 1.17(p), or (Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
[]	under 37 CFR 1.97(i): Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper. (Filed after payment of issue fee)

Statem	ent Unc	er 37 CFR 1.97(<u>e)</u>
[]	any cor	nmunication from	on contained in this Information Disclosure Statement was first cited in m a foreign patent office in a counterpart foreign application not more to the filing of this Information Disclosure Statement; or
[]	knowle in the i	nication from a dge of the under nformation discl	contained in this Information Disclosure Statement was cited in a foreign patent office in a counterpart foreign application, and, to the signed, after making reasonable inquiry, no item of information contained osure statement was known to any individual designated in 37 CFR months prior to the filing of this Information Disclosure Statement.
Statem	ent Unc	er 37 CFR 1.704	(Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29, 2000
[]	commu was no	nication from a received by any	on contained in the Information Disclosure Statement was cited in a foreign patent office in a counterpart application and this communication individual designated in § 1.56(c) more than thirty days prior to the Disclosure Statement.
[X]	Enclos	ed herewith is fo	rm PTO-1449:
	[X]	Copies of the ci	ted references are enclosed.
		[X] Since the and publ	is application was filed after June 30, 2003, copies of issued U.S. patents ished U.S. applications are not required and are not being provided.
	[]	Application No.	ted references are enclosed except those entered in prior application, U.S. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier ains copies of the cited references.]
	[]	The listed refere counterpart fore	ences were cited in the enclosed International Search Report in a ign application.
	[X]	The "concise ex AM3 under 37 (planation" requirement (non-English references) for references AN2 and CFR 1.98(a)(3) is satisfied by:
		[] the expla	anation provided on the attached sheet.
		[] the expla	anation provided in the Specification.
			ion of the enclosed International Search Report.
		[] submiss and/or fo	ion of the enclosed English-language version of a foreign Search Report oreign Office Action.
		[X] the enclo	osed English language abstracts.

[X]	Applic	ant requests that the following non-published pending applications be considered:
Examiner's Initials		
		U.S. Patent Application No. 10/757,981, by Landau <i>et al.</i> , filed January 13, 2004, Docket No.: 3506.1001-002
		U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
		U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
		Examiner Date
	[X]	A copy of the above-cited application, including the current claims, is enclosed.
,	[]	A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.
The Ex	kaminer	r is requested to return a copy of the above list of pending applications indicating which re considered with the next office communication.
It is re	quested	that the information disclosed herein be made of record in this application.
		<u>Remarks</u>
Treaty	ation N Copies are ava	nces AX4 and AY4 are copies of the British priority documents for International o. PCT/GB2003/002974 (WO 2004/004734 A1, published on January 15, 2004, Reference of priority documents for international applications filed under the Patent Cooperation ilable through WIPO upon publication of the international application pursuant to Rule Copies of References AX4 and AY4 were obtained in this manner.
Metho	d of pay	vment:
[]	A checaccom	ck for the fee noted above is enclosed, or the fee has been included in the check with the panying Reply. A copy of this Statement is enclosed.
[]	Please enclos	charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is ed.
[X]	Please	charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.
		Respectfully submitted,
		HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
		Pamela A. Torpey Registration No.: 45,736 Telephone: (978) 341-0036 Facsimile: (978) 341-0136

Concord, MA 01742-9133
Dated: Lebruay, 11, 2004

APPLICATION NO. PTO-1449 REPRODUCED ATTORNEY DOCKET NO. 3506.1000-002 10/757,364 INFORMATION DISCLOSURE CITATION IN AN APPLICATION FILING DATE FIRST NAMED INVENTOR January 13, 2004 Steven B. Landau February 11, 2004 **EXAMINER** CONFIRMATION NO. GROUP Unknown Unknown (Use several sheets if necessary) Unknown

		U.S	S. PATENT DOCUMENTS	
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,695,568	09-22-1987	Ninomiya et al.
	AB	4,939,136	07-03-1990	Haeck et al.
	AC	5,225,407	07-06-1993	Oakley et al.
	AD	5,352,685	10-04-1994	Maruyama et al.
	AE	5,434,174	07-18-1995	Gidda et al.
	AF	5,438,068	08-01-1995	Eeckhout et al.
•	AG	5,470,868	11-28-1995	Young
	АН	5,576,317	11-19-1996	Gonsalves
	AI	5,663,343	09-02-1997	van der Meij et al.
	LΑ	5,945,415	08-31-1999	Kato et al.
	AK	5,962,494	10-05-1999	Young
	AA2	5,977,175	11-02-1999	Lin
	AB2	5,985,866	11-16-1999	Müller et al.
	AC2	5,990,159	11-23-1999	Meulemans et al.
	AD2	6,054,461	04-25-2000	Fairbanks et al.
	AE2	6,117,879	09-12-2000	Fairbanks et al.
	AF2	6,156,771	12-05-2000	Rubin et al.
•	AG2	6,235,745 B1	05-22-2001	Megens
	AH2	6,284,770 B1	09-04-2001	Mangel et al.
	AI2	6,300,336 B1	10-09-2001	Eeckhout et al.
	AJ2	6,355,647 B1	03-12-2002	Steiner et al.
	AK2	6,384,042 B2	05-07-2002	Färber et al.
	AA3	6,429,209 B2	08-06-2002	Mangel et al.
	AB3	6,440,453 B1	08-27-2002	Fischer et. al.
	AC3	6,441,038 B1	08-27-2002	Loder et al.
	AD3	6,458,795 B1	10-01-2002	Bergeron, Jr.

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	WI & SUP		PATENT DOCUMENTS	
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE3	6,465,458 B1	10-15-2002	Wong et al.
	AF3	6,566,369 B2	05-20-2003	Cautreels et al.
	AG3	6,588,708 B1	05-06-2003	Lin
	АН3	2001/0020025 A1	09-06-2001	Megens
	AI3	2001/0044450 A1	11-22-2001	Mangel et al.
	AJ3	2001/0056110 A1	12-27-2001	Faerber et al.
	AK3	2002/0002197 A1	01-03-2002	Mueller et al.
	AA4	2002/0040033 A1	04-04-2002	Cautreels et al.
	AB4	2002/0086880 A1	07-04-2002	Rubin et al.
	AC4	2002/0086881 A1	07-04-2002	Rubin et al.
	AD4	2002/0107244 A1	08-08-2002	Howard, Jr.
	AE4	2003/0125349 A1	07-03-2003	Cautreels et al.
	AF4	2003/0203055 A1	10-30-2003	Rao et al.
	AG4	6,593,336 B2	07-15-2003	Mangel et al.
	AH4	2003/0036549 A1	02-20-2003	Mangel et al.
	AI4	6,211,171 B1	04-03-2001	Sawynok et al.
	AJ4	5,530,008	06-25-1996	Azcona et al.
	AK4	5,977,127	11-02-1999	Bonnacker et al.
	AA5	4,845,092	07-04-1989	Sanger et al.

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		FOREIGN PATENT D	OCUMENTS		
	DOCUMENT NUMBER Country Code-Number-Kind Code (if known) DATE MM-DD-YYYY NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT TRANSLATIC YES NO				LATION NO
AL	WO 01/26623 A3	04-19-2001	Laxdale Limited		
AM	EP 1 230 921 A1	08-14-2002	Pfizer Products, Inc.		
AN	WO 02/083926 A3	10-24-2002	Cedars-Sinai Medical Center		
AO	WO 00/48597	08-24-2000	Novartis AG		
AP	WO 00/48581 A3	08-24-2000	Novartis AG		
AQ	WO 00/51583	09-08-2000	Sepracor, Inc.		
AL2	WO 2004/004734 A1	01-15-2004	Arachnova Therapeutics Ltd.		
AM2	WO 00/51584	09-08-2000	Sepracor, Inc.		
AN2	WO 02/07713 A2	01-31-2002	Solvay Pharmaceuticals GMBH	- :	X
AO2	EP 0 297 651 B1	01-04-1989	Duphar International Research B.V		
AP2	WO 02/094249 A1	11-28-2002	Arachnova Therapeutics Ltd.		
AQ2	WO 03/077897 A1	09-25-2003	Cypress Bioscience, Inc.		
AL3	WO 94/01095 A3	01-20-1994	Smith-Kline Beecham PLC		
AM3	WO98/50037	11-12-1998	Mitsubishi Chemical Corporation		Х
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February 11, 2004 See several sheets if necessary)	examiner Unknown	CONFII Unkn	RMATION NO. OWN	group Unknown	

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AR	Depoortere, I., et al., "Dose-Dependent Effects of Recombinant Human Interleukin-11 on Contractile Properties in Rabbit 2,4,6-Trinitrobenzene Sulfonic Acid Colitis ¹ ," J. Pharmacol. Exp. Ther., 294(3): 983-990 (2000).
AS	Million, M., et al., "Susceptibility of Lewis and Fischer Rats to Stress-induced Worsening of TNB-colitis: Protective Role of Brain CRF," Amer. Phys. Soc., 276 (4 Pt 1): G1027-G1036 (1999).
АТ	Owens, M. J., et al., "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and their Metabolites ¹ ," J. Pharmacol. Exp. Ther., 283(3): 1305-1322 (1997).
- AU	Kozlowski, C.M., et al., "The 5-HT ₃ Receptor Antagonist Alosetron Inhibits the Colorectal Distention Induced Depressor Response and Spinal c-fos Expression in the Anaesthetised Rat," Gut, 46: 474-480 (2000).
AV	Ito, C., et al., "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)methyl]- benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine ₃ Receptor Antagonist, on Colonic Function in Rats," J. Pharmacol. Exp. Ther., 280(1): 67-72 (1997).
Eguchi, J., et al., "Pharmacological Profile of the Novel Antidepressant 4-(2-Fluorophenyl)-6 (1-piperazinyl)thieno-[2,3-d]pyrimidine Monohydrate Hydrochloride," Arzneimittelforschung 1337-1347 (1997).	
AX	Venkova, K., et al., "Peripheral Activity of a New NK ₁ Receptor Antagonist TAK-637 in the Gastrointestinal Tract," J. Pharmacol. Exp. Ther., 300(3): 1046-1052 (2002).
. AY	Yuan, S.Y., et al., "Investigation of the Role of 5-HT ₃ and 5-HT ₄ Receptors in Ascending and Descending Reflexes to the Circular Muscle of Guinea-pig Small Intestine," Br. J. Pharmacol., 112(4): 1095-1100 (1994).
. AZ	Jin, J.G., et al., "Propulsion in Guinea Pig Colon Induced by 5-Hydroxytryptamine (HT) Via 5-HT ₄ and 5-HT ₃ Receptors ¹ ," J. Pharmacol. Exp. Ther., 288(1): 93-97 (1999).
AR2	Greenbaum, D.S., et al., "Effects of Desipramine on Irritable Bowel Syndrome Compared with Atropine and Placebo," Digestive Diseases and Sciences, 32(3): 257-266 (1987).
AS2	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996.

EXAMINER	DATE CONSIDERED	1	
		<u> </u>	

PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 3506.1000-002			PLICATION NO. 1/757,364	
February 11, 2004 (Use several sheets if necessary)	FIRST NAMED INVENTOR Steven B. Landau		FILING DATE January 13, 2004		
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18/0/8/1	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AT2	Eguchi, J., et al., "The Anxiolytic-Like Effect of MCI-225, A Selective NA Reuptake Inhibitor with 5-HT ₃ Receptor Antagonism," <i>Pharm. Biochem. and Behavior</i> , 68:677-683 (2001).
AU2	Schmulson, M.J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> , 3:104-110 (2001).
AV2	Camilleri, M., "Serotonergic Modulation of Visceral Sensation: Lower Gut," Gut 51(1):81-86 (2002).
AW2	Camilleri, M., "Serotonergic Drugs: Emerging Therapies for Irritable Bowel Syndrome," In <i>Irritable Bowel Syndrome a Clinician's Guide</i> , M. Camilleri and R. C. Spiller, eds., Chapt. 19; pp 1-10 (2002).
AX2	Wood, J.D., et al. "Fundamentals of Neurogastroenterology," Gut 45(2):II6-II16 (1999).
AY2	Burns, M.J., "The Pharmacoloty and Toxicology of Reboxetine," Int. J. Med. Toxicol. 3(4):26 1-8 (2000).
AZ2	Thompson, W.G., et al., "Functional Bowel Disorders and Functional Abdominal Pain," Gut 45:II43-II47 (1999).
AR3	Sheikh, M. Y. and Wright, R.A., "Irritable Bowel Syndrome: Current Concepts and Future Prospects," <i>Hospital Physician</i> , pp. 31-38 (March 1999).
AS3	Schmulson, M.J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> 3:104-110 (2001).
AT3	Gebhart, G.F., "Pathobiology of Visceral Pain: Molecular Mechanisms and Therapeutic Implications IV. Visceral Afferent Contributions to the Pathobiology of Visceral Pain," Am. J. Physiol. Gastrointest. Liver Physiol. 278:G834-G838 (2000).
AU3	Mertz, H.R., "Irritable Bowel Syndrome," N. Engl. J. Med. 349:2136-2146 (2003).
AV3	Bymaster, F.P., et al. "Comparative Affinity of Duloxetine and Venlafaxine for Serotonin and Norepinephrine Transporters In Vitro and In Vivo, Human Serotonin Receptor Subtypes, and Other Neuronal Receptors," Neuropsychopharmacology, 25(6):871-880 (2001).
AW3	Béïque, J.C., et al., Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," Eur. J. Pharmacol., 349(1):129-132 (1998).

EXAMINER	DATE CONSIDERED	1
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PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 3506.1000-002 APPLICATION NO. 10/757,364			
FEB (Seeveral sheets if necessary)	FIRST NAMED INVENTOR Steven B. Landau FILING DATE January 13		FILING DATE January 13,	2004
	examiner Unknown		RMATION NO. NOWN	GROUP Unknown

	CALL TIME	
	1	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	AX3	Wong, E.H.F., et al., "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," Biol. Psychiatry. 47(9): 818-829 (2000).
	AY3	Sach, J.A., et al., "Irritable Bowel Syndrome," Curr. Treat. Options. Gastroenterol., 5(4): 267-278 (2002).
	AZ3	Angel, I., et al. "Litoxetine: A Selective 5-HT Uptake Inhibitor with Concomitant 5-HT ₃ Receptor Antagonist and Antiemetic Properties," Eur. J. Pharmacol., 232(2-3):139-145 (1993).
•	AR4	Fairweather, D.B., et al., "The Psychomotor and Cognitive Effects of Litoxetine in Young and Middle Aged Volunteers," Br. J. Clin. Pharmacol., 40(2):119-125 (1995).
	AS4	Morteau, O., et al., "Influence of 5-HT ₃ Receptor Antagonists in Visceromotor and Nociceptive Responses to Rectal Distension Before and During Experimental Colitis In Rats," Fundam. Clin. Pharmacol., 8(6):553-562 (1994).
	AT4	Goldberg, P.A., et al., "Modification of Visceral Sensitivity and Pain in Irritable Bowel Syndrome by 5-HT ₃ Antagonism (Ondansetron)," <i>Digestion</i> , 57(6):478-483 (1996).
	AU4	LOTRONEX - Tablets, <i>Product Information</i> , GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).
	AV4	"Irritable Bowel Syndrome at a Glance - Nosology, Epidemiology, and Pathophysiology (Monograph I), December 2002 [Retrieved on 2002-12-12]. Retrieved from the Internet <url:http: education="" fdhn.org="" gi="" html="" ibs_nosology.htm=""></url:http:>
	AW4	U.S. Provisional Application No. 60/364,531, filed 03-15-2002, entitled "Methods of Treating Visceral Pain Syndromes," by Rao <i>et al.</i> , priority document for WO 03/077897 A1 (Reference AQ2) and U.S. 2003/0203055 A1 (Reference AF4).
	AX4	GB 0304648.9, filed 02-28-2003, entitled "New Therapeutic Use of 4-(2-Fluorophenyl)-6-Methyl-2-(1-Piperzinyl) Thieno[2,3-D] Pyrimidine," priority document for WO 2004/004734 A1 (Reference AL2).
	AY4	GB 0216027.3, filed July 10, 2002, entitled "New Therapeutic Use," priority document for WO 2004/004734 A1 (Reference AL2).
	AZ4	Drossman, D.A., et al., "Irritable Bowel Syndrome: A Technical Review for Practice Guideline Development," Gastroenterology, 112: 2120-2137 (1997).

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